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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: **Benjamin W. Boldt** )  
and **Dennis Roscetti** )  
Serial No.: 09/109,119 )  
Filed: 06/30/98 )  
Group Art Unit: 1653 )

Examiner: **Anna Pawul**

For: **A Process For Detecting A Known Sequence In Genomic DNA**

AMENDMENT UNDER 37 C.F.R. § 1.111

Commissioner of Patents  
and Trademarks  
Washington, D.C. 20231

Dear Sir:

This Amendment responds to the Office Action dated September 7, 1999. Kindly amend the application as follows:

In the Claims:

Please amend claims 1, 8, 13 and 16 as follows:

Sub  
B1  
A1

- I. (Amended) A process for testing genomic DNA for conditions, whether inherited or not inherited, comprising:
- a) making a solution comprising the genomic DNA;
  - b) adding a primer substantially complementary to a diagnostic section of the genomic DNA, selected from the group consisting of a primer having no mismatch bases and a primer having at least one mismatch base, relative to the diagnostic section;
  - c) mixing a DNA polymerase into the solution;
  - d) efficiently amplifying the diagnostic section if no mismatch is present;
  - e) capturing amplified polynucleotide strands to a solid support; and, detecting captured amplified polynucleotide strands.

A2 8. (Amended) The process of claim 7 wherein [step g comprises] a further step is added comprising adding a reporter label to the solution.

Subt B2  
A3 13. (Amended) A process for detecting a mismatch base in a diagnostic section of genomic DNA for conditions, whether inherited or not inherited, comprising:

- a) obtaining the genomic DNA;
- b) mixing the genomic DNA with a primer substantially complementary to the diagnostic section of the genomic DNA, selected from the group consisting of a primer having no mismatch bases and a primer having at least one mismatch base, relative to the diagnostic section;
- c) efficiently [selectively] amplifying the diagnostic section from the genomic DNA if no mismatch is present;
- d) capturing amplified polynucleotides to a solid support; and quantifying any complex attached to the solid support.

A4 16. (Amended) The process of claim 15 further comprising attaching a reporter label to the complex for quantifying [presence of] the complex.

### REMARKS

#### Objection to the Specification under 35 U.S.C. 112:

Claims 1, 8, 13, 16 and 17 have been rejected under §112. Applicants respectfully disagree with the rejection.

On page 2 of the Office Action, in paragraph 3, an objection is made to the term "substantially complementary" found in the claims. Applicants' have defined the term in the specification on page 12, line 28 to page 13, line 8 as:

"the primers herein are selected to be substantially complementary to the different strands of each specific sequence to be amplified. This means that the primers must be sufficiently complementary to hybridize with their respective strands. Therefore, the primer sequence need not reflect the exact sequence of the template. For example, where the primer comprises a nucleotide sequence in which the 3'-terminal nucleotide is complementary to either the suspected mismatch nucleotide or the corresponding normal nucleotide a non-complementary nucleotide fragment may be attached to the 5'-end of the primer, with the remainder of the primer sequence being complementary

to the diagnostic section of the target base sequence. Commonly the primers are complementary except when non-complementary nucleotides may be present at a predetermined primer terminus as described."

The nature of Applicants' invention involves hybridization of a primer to a specific gene sequence when none or at least one mismatch is present. There can be more than one mismatch and the specification provides for such circumstances. The specification clearly defines substantially complementary as meaning the primer may have one or more base mismatches yet still hybridize to its complementary gene strand. The scope is clear because if there are too many mismatches, the primer will not hybridize as has been contemplated.

In paragraph 4, an objection is made to the term "diagnostic section" as being indefinite. Applicants' point to page 11, lines 10-20 as clearly defining the terminology. The diagnostic section is defined as a specific portion of the target molecule.

In paragraph 5, an objection is made to the term "quantifying presence of the complex" in claim 16. Applicants' agree that the terminology is not clear and have amended the claim to clarify the meaning.

Paragraph 6 objects to terminology in claim 8. Applicants have amended claim 8 to comply with the suggestion in the Office Action.

Applicants respectfully request that the §112 be removed based upon the material in the specification and the amendments made to clarify the claims.

Rejection of claims 1-20 under 35 U.S.C. 102:

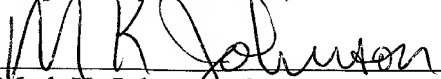
Claims 1-20 have been rejected under §102 (e) as being anticipated by Harris et al., U.S. Patent No. 5,849,544. Applicants respectfully disagree with the rejection.

Applicants have amended independent claims 1 and 13 to clearly point out the differences from the prior art cited. Harris et al. performs amplification that is not dependent upon a base mismatch at or near the 3' end of their primer. In contrast, Applicants' invention is based upon an efficient amplification if no mismatch is present and no or inefficient amplification if at least one mismatch is present. The claims have been amended to illustrate this difference.

A §102 (e) prior art must show each and every element of the claims. Applicants point out that their claimed elements are not shown in the Harris et al. patent. Therefore, Applicants believe that the rejection has been obviated.

The Examiner's objections and rejections are now believed to be overcome by this response to the Office Action. In view of Applicants' amendment and arguments, it is submitted that the claims 1-20 should be allowable and Applicants respectfully requests an early notice to such effect.

Respectfully submitted,



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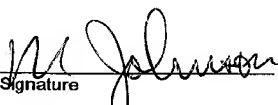
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